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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,161	08/24/2001	Richard W. Voellmy		4118

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EXAMINER

OH, SIMON J

ART UNIT	PAPER NUMBER
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1618

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/939,161

Applicant(s)

VOELLMY, RICHARD W.

Examiner

Simon J. Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-91 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's amendment, response, request for continued examiner and information disclosure statement, all received on 30 October 2006.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 30 October 2006 has been entered.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 30 October 2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Claim Rejections - 35 USC § 101 and 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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The rejection of Claims 26-33 under 35 U.S.C. 101 is rendered moot with the cancellation of those claims.

The rejection of Claims 26-33 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is rendered moot with the cancellation of those claims.

Claims 34, 36-42, 50, 52-58, 75, 77-83 and 91 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The administration of the instantly recited heat dose by heating hair follicles of the scalp of a human patient or the skin of a mammalian animal at about 39°C to 45°C for about 15 to 120 minutes is critical or essential to the practice of the invention, but not included in the claims. As such, the instant claims in their present form are not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The aforementioned heat dose is described by the specification as requiring the parameters recited above in order to effect the increase in Hsp expression and concentration (See Lines 14-17 on Page 20 of the specification). No evidence is found within the instant specification that the instantly claimed methods can be practiced without these parameters. Therefore, the absence of such claim limitations in the instant claims is seen as missing essential subject matter.

Claims 34-91 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The administration of a chemotherapeutic drug within 2 to 24 hours after the administration of the instantly recited heat dose is critical or essential to the practice of the invention, but not included in the claims. As such, the instant claims in their present form are

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not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The aforementioned heat dose is described by the specification as resulting in a relatively rapid increase in Hsp expression and concentration within 2 to 24 hours after the treatment (See bottom of Page 5 of the specification). Therefore, the chemotherapeutic drug should be administered during this period of time (See sentence bridging Pages 5 and 6). No evidence is found within the instant specification that the instantly claimed methods can be practiced without this guideline. Therefore, the absence of such claim limitations in the instant claims is seen as missing essential subject matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 34, 36, 39, 50, 52, 55, 75, 77 and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Li *et al.* (U.S. Patent No. 5,830,177)

The Li *et al.* patent teaches compositions and treatment methods useful for the prevention of hair loss during chemotherapy. In a preferred embodiment, a nucleic acid comprising an expression vector capable of expressing human p-glycoprotein is administered to a subject (See Column 4, Lines 39-62). Methods of administration also include the utilization of electromagnetic radiation, including infrared radiation (See Column 5, Lines 58-66). The open scope of the instant claims, and further in view of the lack of specificity with which the method

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step of administering heat to a patient is described, the limitations of the instant claims are therefore met.

Response to Arguments

The previously rejected claims have now been cancelled by the applicant and are now replaced with new Claims 34-91. The rejections on now cancelled Claims 26-33 have been therefore rendered moot. The examiner has found new grounds for rejection on new Claims 34-91, thereby rendering the applicant's own arguments moot as well.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

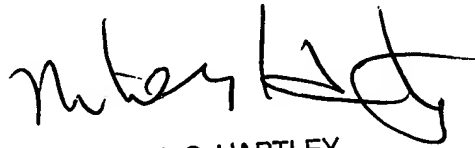
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Simon J. Oh
Examiner
Art Unit 1618

sjo



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER